GIBBONS

CHARLES H. CHEVALIER
Director

Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Direct: (973) 596-4611 Fax: (973) 639-6263
cchevalier@gibbonslaw.com

February 3, 2025

VIA ECF

The Honorable Brian R. Martinotti
United States District Judge
Martin Luther King Jr. Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

[redacted]

Re: ***In re Selenious Acid Litigation*, No. 2:24-cv-07791-BRM-CLW (Consolidated)**

Dear Judge Martinotti:

We, along with Sterne, Kessler, Goldstein & Fox P.L.L.C., represent Plaintiff American Regent, Inc. ("ARI") in the above-referenced matter. On January 17, 2025, ARI moved for a preliminary injunction ("PI") to enjoin the eleven consolidated Defendants in this case[1] from flooding the market with infringing generic selenious acid ANDA Products and irreparably harming ARI [redacted] and before a trial can occur. *See* ECF No. 85, 95. As set forth in ARI's PI motion, ARI had previously attempted to minimize the burden on this Court and avoid emergency briefing regarding Defendants' likely at-risk launch—e.g., by seeking an expedited case schedule, early production of samples, advanced notification of launch, an orderly PI briefing schedule, etc.—yet Defendants refused each of these efforts. *See* ECF No. 95 at 9–10. Only after this Court's January 6, 2025 Order did the parties commence briefing the PI issue. ECF No. 59.

As a result of Defendants' delays, ARI's PI motion almost certainly will not be resolved before Defendants' [redacted] The Court ordered that the PI briefing be completed by February 24, but no hearing has been set. *See* ECF No. 59. Accordingly, ARI reached out to Defendants on January 30, 2025 to confirm whether Defendants would agree to [redacted], yet Defendants have failed to answer. Thus, ARI respectfully writes pursuant to the Court's Judicial Preferences

[1] Accord Healthcare, Inc. (2:24-cv-07791); Aspiro Pharma Ltd. (2:24-cv-07794); Cipla USA, Inc. (2:24-cv-07796); Dr. Reddy's Lab'ys, Ltd. (2:24-cv-07799); Gland Pharma Ltd. (2:24-cv-07802); Hikma Pharms. USA, Inc. (2:24-cv-07803); RK Pharma, Inc. (2:24-cv-07805); Somerset Therapeutics, LLC (2:24-cv-07807); Sun Pharm. Indus. Ltd. (2:24-cv-07810); Xiromed, LLC (2:24-cv-07811); and Zydus Pharms. (USA) Inc. (2:24-cv-07812).

to request that the Court issue a stay order maintaining the status quo and preventing Defendants from [redacted].[2]

After separately consulting with Your Honor during the January 6, 2025 status conference, Judge Waldor indicated to the parties that the Court might not be able to hear oral arguments regarding ARI's PI motion until the end of March 2025. [redacted] Even this short window of infringing generic competition would irreparably harm ARI; thus, justifying keeping Defendants off the market until ARI's PI motion can be heard so as to preserve the status quo.

Specifically, and as set forth in ARI's PI brief, each of the four requisite factors—likelihood of success on the merits, immediate irreparable harm, balance of hardships, and the public interest—weighs in favor of an order temporarily preserving the status quo. *See Great Caesars Ghost LLC v. Unachukwu*, No. 19-5408, 2019 WL 1515156, at *1 (D.N.J. Feb. 19, 2019) ("a court may issue a temporary restraining order [] when 'there is a possibility that irreparable injury will occur before the hearing on a preliminary injunction'" and the standard "is the same as that used" for issuing a preliminary injunction).

First, as discussed in detail in its PI brief (ECF No. 95 at 12–27), ARI is likely to succeed on the merits. For infringement, there is no real dispute that [redacted] *Id.* at 12–19. Nor can Defendants raise the required substantial question of validity. The Patent Office has already repeatedly considered the same or substantially the same prior art and arguments that Defendants are likely to rely on in this case, and yet still allowed the claims. *Id.* at 19–25. There is also compelling objective evidence of non-obviousness. *Id.* at 25–27.

Second, ARI would suffer immediate irreparable harm should Defendants be permitted to launch their infringing ANDA Products before a PI hearing, even if Defendants' are ordered to

[2] Should the Court prefer, ARI is prepared to promptly file a formal motion for temporary restraining order to [redacted] ARI filed the instant letter simply to reduce the burden on the Court and to avoid unnecessary briefing. This Court has ordered this type of requested relief before. *See, e.g.*, *Novartis Corp. et al. v. Teva Pharms. USA, Inc.*, No. 2:04-cv-04473-HAA-ES, ECF No. 56 (May 19, 2007); *In re Depomed Pat. Litig.*, No. 2:13-cv-04507-CCC-MF, ECF No. 468 (May 18, 2016).

cease selling their ANDA Products shortly thereafter. As detailed in ARI's opening PI brief, given the unique nature of the Selenious Acid market involving [redacted] and a web of statutes and regulations, permitting Defendants to enter the market for even a few days will likely cause a cascade of price erosion and lost contracts, resulting in [redacted] *Id.* at 27–34. As also explained in ARI's opening brief, this harm, even from a short window of premature generic competition, [redacted]. *Id.* at 33–37. The moment ARI [redacted] in response to the initial flood of selenious acid generic products, [redacted] As a consequence, [redacted] without Defendants' [redacted] entry. *Id.* at 34, 36–37. And because Defendants' generic ANDA Products would likely [redacted] immediately upon entry, and so [redacted] *Id.* And importantly, [redacted], [redacted]. Thus, even days of premature generic competition from Defendants is poised to cause immediate irreparable harm.

Third, the balance of hardships weighs heavily in ARI's favor. The harm to ARI will, for as explained above, be substantial and irreparable. In contrast, Defendants' hardship is minimal. Because ARI seeks only to preserve the status quo for the short interim period—until the Court can decide the PI motion—Defendants will only be prevented from entering the selenious acid market for a short period of time if the Court denies ARI's PI motion. *Id.* at 38–39. On the other hand, if the Court grants ARI's PI motion, then there is no cognizable harm to Defendants at all, since Defendants do not have a right to enter the market with an infringing product. *Id.* at 39. Further, as set forth above, ARI repeatedly sought to prevent this precise situation requiring emergency and temporary relief by requesting, e.g., an expedited schedule, advanced notice of launch, and an orderly and early PI briefing schedule, yet Defendants rejected all of ARI's efforts. Thus any purported harm to Defendants by keeping the status quo until the PI hearing is entirely self-inflicted and cannot be used to overcome the necessary, temporary relief that ARI seeks. Nevertheless, because Defendants are not yet on the market, a stay would maintain the status quo.

Fourth, the public interest weighs in favor of ARI. The public greatly benefits from ARI's significant investments to develop its improved and patented Selenious Acid product. *Id.* at 40. If the Court does not at least temporarily prevent Defendants from entering ARI's patent-protected market with their discounted and infringing generics and cause irreparable harm to that market, the incentives for costly innovation like ARI's will be lost. *Id.* The public interest thus clearly favors maintaining the status quo.

Because all injunctive relief factors weigh in ARI's favor, and because granting ARI's requested relief will simply maintain the status quo, ARI respectfully requests that the Court enjoin Defendants from launching their ANDA Products until the Court can issue its ruling on ARI's PI motion.

We thank Your Honor for your kind attention to this matter.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier
Counsel for Plaintiff American Regent, Inc.

cc: Counsel of record via e-mail